

REMARKS

Applicants wish to thank the Examiner for the review of the present application. Applicants have amended claims 1, 7, 10, 15, 18, 21-22, 55, 57, 58, 60, 61, 69, 85, 86, 94, 96-103, 106, 108-114, 118, 121, 128, 129, 132-137, 144, 145, 148-153, and 190. Applicants have also added new claims 228-256. Claims 2-6, 8-9, 11-14, 16-17, 23-54, 62-65, 72-84 and 87-93 were previously cancelled, and claims 154-189 and 191-227 are herein cancelled by the present amendment. Claims 1, 7, 10, 15, 18-22, 55-61, 66-71, 85-86, 94-153, 190, and 228-256 are now pending in the application. No new matter has been added.

Claim Rejections – 35 U.S.C. § 112

Claims 1, 7, 10, 15, 18-22, 55-61, 66-71, 85-86, and 94-227 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. Primarily, the Examiner has rejected these claims due to the recitation of the term “therapy.” Applicants disagree with the Examiner’s definition of the term therapy as used in the office action, because the use of the term is inconsistent with and narrower than the definition used in the field of medicine. However, the Applicants have amended the claims to remove the term in order to expedite allowance of the claims.

Similarly, the recitation of “a thickness similar to that of normal articular cartilage adjacent to diseased articular cartilage” to which the Examiner objected has been removed from claim 1 as amended.

35 U.S.C. § 101

The Office Action rejects claims 1, 7, 10, 15, 18-22, 55-61, 66-71, 85-86 and 94-227 under 35 U.S.C §101 as being directed to non-statutory subject matter.

35 U.S.C. §101 states, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” The

categories of invention are thereby defined as a process, machine, manufacture and composition of matter. The Supreme Court has further stated that “Congress intended statutory subject matter to “include anything under the sun that is made by man.”” *Diamond v. Diehr*, 450 U.S. 175, 182 (1981). In that case, the Supreme Court said:

That a process may be patentable, irrespective of the particular form of the instrumentalities used, cannot be disputed. . . . A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject matter to be transformed and reduced to a different state or thing. If new and useful, it is just as patentable as is a piece of machinery.

Diamond v. Diehr, 450 U.S. 175, 182-184 (1981) (citing *Cochrane v. Deener*, 94 U. S. 780, 787-788 (1877).

As amended, the claims are patentable under the law as outlined above, because each of these claims requires the transformation of information into a new, useful and tangible result. For example, Applicants have amended each of the independent claims to recite a process that transforms information to produce a tangible result, i.e., an implant or a physical model. Claims 1 and 10 each require obtaining information from image data of a joint and creating an implant from the information. Claim 153 requires obtaining information from image data of a joint and forming a physical model from the information. Claim 190 requires obtaining information from image data of a joint and creating a physical model.

Similarly, claims 7, 15, 18-22, 55-61, 66-71, 85-86 and 94-152 are each patentable for the same reasons, because each depends, either directly or indirectly, from claim 1 or claim 10. Thus, all of the pending claims in this application are patentable pursuant to 35 U.S.C. § 101.

35 U.S.C. §103(a)

Claims 1, 7, 10, 15, 18-19, 21-22, 55-58, 60-61, 66-71, 85-86, 94-156, 158-194 and 196-227 stand rejected as unpatentable over U.S. Patent No. 5,682,886 (Delp et al., hereinafter “Delp”) in view of U.S. Patent Number 6,161,080 (Aouni-Ateshian et al., hereinafter “Aouni-

Ateshian”), U.S. Patent No. 5,320,102 (Paul et al., hereinafter “Paul”) and U.S. Patent No. 6,835,377 (Goldberg et al., hereinafter “Goldberg”). Claims 20, 59, 157 and 195 similarly stand rejected as unpatentable over these same references in further view of U.S. Patent No. 6,175,655 (George, III et al., hereinafter “George, III”)

Collectively, the references cited by the Examiner disclose methods of medical imaging, modeling joints and treating cartilage. However, none of the references – either alone or in combination – discloses obtaining image data of a joint and generating a patient-specific device having an articular surface that is based on the information from the image data. Specifically, all of the independent claims in this application have been amended to recite devices in which an outer, articular surface of the device is derived from image data of a joint. In claim 1, the outer surface is created based on information concerning cartilage or subchondral bone that is obtained from the image data. In claim 10, the outer surface is created based on information concerning cartilage that is obtained from the image data. In claims 153 and 190, the outer surfaces are formed or created based on information about the underlying subchondral bone of the joint.

None of the art cited by the Examiner discloses these features of the amended claims. Delp, for example, primarily discloses a surgical planning system that can be used with existing implants to plan surgeries or assist in robotic surgeries. Delp, however, does not disclose a system that can be used to create implants or physical models based on the image data that is used. In fact, Delp explicitly states that the implants used in conjunction with the surgical planning methods are those that are commercially available, and further states that the structure of these implants are not important.

It is intended that the invention can be used with any commercially-available prosthesis, whether standard or custom-designed, and *the structure of the prosthesis is not important* except that data representing its size and configuration must be loaded into the planning software in order to provide accurate sizing and placement information and useful planning information.

(See Delp, col. 12, lines 47-61 (emphasis added).) Thus, not only does Delp not disclose the methods of forming and creating implants and physical models as claimed, Delp actually teaches away from such concepts by explicitly stating that the structure of such devices is not important.

Similarly, Aouni-Ateshian employs images of joints, but does not specifically disclose any particular type of implant that is designed. Instead, Aouni-Ateshian primarily discloses using image data to create virtual models of joints. With regard to designing prostheses, Aouni-Ateshian discloses only that “[p]rotheses and other medical instruments may be more efficiently designed and evaluated using a model.” (See col. 1, lines 62-64.) Aouni-Ateshian fails to disclose any detail about the structure of such prostheses. More specifically, Aouni-Ateshian fails to disclose or suggest that an implant or physical model may be created or formed with an outer surface based on the geometry of a particular joint.

Goldberg also fails to disclose the methods as claimed, and, instead, discloses very different technology. Goldberg is directed to the regeneration of cartilage using, for example, “a suspension of purified fibrillar collagen or modified collagen and culture-expanded human mesenchymal stem cells (hMSCs).” (Goldberg Col. 5, lines 48-50.) Goldberg states in the abstract that the invention is “[f]or repair of cartilage damaged as part of the degenerative effects of osteoarthritis” and that “the inventors have found that the human mesenchymal stem cell approach makes it possible to [among other things] regenerate both shallow cartilage chondral defects and full thickness cartilage defects...” Goldberg does not disclose implants or physical models as claimed. Thus, nothing in Goldberg would cause one skilled in the art to combine the references with any other references to obtain the claimed inventions.

Paul similarly fails to disclose all of the claimed elements of the independent claims. As noted in the abstract, Paul uses MRI images to diagnose proteoglycan deficiency in articular cartilage. Paul does not disclose any implants or physical models, as those concepts are absent from the specification. More specifically, Paul does not teach or suggest all of the elements of the claims as amended, and nothing in Paul would cause one skilled in the art to combine that reference with others to create the claimed methods.

Finally, as with the other cited art, George, III does not teach or suggest the claimed methods, and nothing in that reference would cause one skilled in the art to combine that reference with others to create the claimed methods. George, III discloses methods of generating and manipulating three-dimensional images from MRIs and other medical images, but does not disclose the creation or formation of implants and physical models using those images. Thus,

George does not teach or suggest the independent claims as amended.

Claims 7, 15, 18-22, 55-61, 66-71, 85-86 and 94-152, and new claims 228-256, are each patentable for at least the same reasons, because they depend from independent claims 1, 10, 153, or 190. Thus, all of the pending claims in the application are patentable over each of, and every combination of, Delp, Aouni-Ateshian, Goldberg, Paul, and George, III.

CONCLUSION

All pending claims are believed to be in a form suitable for allowance. Therefore, the application is believed to be in a condition for allowance. The Applicants respectfully request early allowance of the application. The Applicants also request that the Examiner contact the undersigned, if it will assist further examination of this application.

Applicants believe that a three month extension of time is required, and hereby request that the associated fees be charged to Deposit Account No. 19-4972. Applicants also request that any other fee required for timely consideration of this application be charged to Deposit Account No. 19-4972.

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Respectfully submitted,

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